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1 RECORD OF ORAL HEARING  
2  
3 UNITED STATES PATENT AND TRADEMARK OFFICE  
4

5  
6 BEFORE THE BOARD OF PATENT APPEALS  
7 AND INTERFERENCES  
8

9  
10 Ex parte HANS-URICH PETEREIT, THOMAS BECKERT,  
11 MANFRED ASSMUS, WERNER HOESS, WOLFGANG FUCHS, and  
12 HARTMUT SCHIKOWSKY  
13

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15 Appeal 2007-4001  
16 Application 09/913,720  
17 Technology Center 1600  
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20 Oral Hearing Held: January 22, 2008  
21

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23  
24 Before DONALD E. ADAMS, LORA M. GREEN, and RICHARD M.  
25 LEBOVITZ, *Administrative Patent Judges*.  
26

27 ON BEHALF OF THE APPELLANTS:  
28

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35 The above-entitled matter came on for hearing on Tuesday, January  
36 22, 2008, commencing at 9:54 a.m., at the U.S. Patent and Trademark  
37 Office, 600 Dulany Street, Alexandria, Virginia, before Janice A. Salas,  
38 Notary Public.

1 THE CLERK: Calendar Number 34, Appeal Number 2007-  
2 4001, Mr. Doughty.

3 JUDGE ADAMS: Is it Mr. Doughty or Mr. Doughty?

4 MR. DOUGHTY: Doughty.

5 JUDGE ADAMS: And if you wouldn't mind, could you take a  
6 moment and spell your name for the record.

7 MR. DOUGHTY: Sure. That's D-O-U-G-H-T-Y, Doughty.  
8 My first name is Jacob.

9 JUDGE ADAMS: And we've considered the record and you  
10 have 20 minutes, and you can begin when you're ready.

11 MR. DOUGHTY: Thank you. May it please the Board, my  
12 name is Jacob Doughty and I represent the appellants in this matter. Good  
13 morning, Your Honors.

14 Claim 1, the only independent claim subject to appeal right  
15 now, is a method claim and it includes four steps. There's melting of the  
16 particular monomer mixture, devolatilizing the molten mixture, injecting the  
17 mixture into a mold and removing the molded product.

18 The polymer mixture includes a polymer based on C1 to C4  
19 alkyl esters of acrylic or methacrylic acid and the mixture further includes a  
20 release agent in a small amount.

21 This process is an improvement on the process disclosed in the  
22 primary reference Lehmann, which is owned by the same assignee as the  
23 present application.

24 JUDGE LEBOVITZ: So when you say it's an -- maybe you're  
25 getting to it and I apologize, but when you say it's an improvement, I just  
26 want to establish that it looks like what the examiner is alleging here is that

1 you've got the same polymer, you've got a release agent, but what's lacking  
2 is the devolatilization step.

3 MR. DOUGHTY: That's right.

4 JUDGE LEBOVITZ: And the examiner is saying Vetter uses  
5 devolatilization, so it would be obvious to have applied that step to  
6 Lehmann's polymer mixture.

7 MR. DOUGHTY: That's correct.

8 JUDGE LEBOVITZ: Correct?

9 MR. DOUGHTY: Yep.

10 JUDGE LEBOVITZ: So that will be the point that you'll be  
11 addressing today?

12 MR. DOUGHTY: Absolutely.

13 So as we're just discussing, the improvement of the invention  
14 claim 1 over Lehmann is devolatilizing the mold mixture, okay; otherwise,  
15 the methods are virtually the same, as you point out.

16 The examiner in the case admits that Lehmann doesn't disclose  
17 devolatilizing as provided in claim 1.

18 The examiner looks to the Vetter reference to remedy this  
19 deficiency in Lehmann. Vetter discloses a process like the process of  
20 Lehmann and the process of claim 1 in which a polymer mixture is melted.  
21 The mixture is injected into a mold and a molded product is removed from  
22 the mold.

23 Vetter, unlike Lehmann, includes a step of devolatilizing the  
24 melted polymer mixture; however, the devolatilization step employed in  
25 Vetter is used to solve a problem that doesn't exist in Lehmann.

26 In particular, in Vetter, a volatile liquid treatment agent, like for

1 -- in most of the examples, it's an ammonia or an amine -- is added to the  
2 melted polymer mixture and then must subsequently be driven off, okay?

3           So in Lehmann, there is no volatile liquid treatment agent that  
4 is added to the polymer mixture, and thus, there's no reason to conduct  
5 devolatilization to remove a volatile liquid treatment agent.

6           So according to the modified Lehmann in the way that the  
7 examiner proposes is to add a superfluous step. There's nothing in either of  
8 the references indicating that such a step would have any value in the  
9 method -- in a method such as disclosed in Lehmann.

10           So obviousness, the concept of obviousness has developed  
11 recently, particularly in view of the case, our case, but there still needs to be  
12 an apparent reason to combine known elements to obtain the claimed  
13 combination.

14           JUDGE LEBOVITZ: Well, what about this. I mean, Vetter, I  
15 think -- number 1, I think Vetter's disclosure is broader. He said to remove  
16 any impurities.

17           MR. DOUGHTY: True.

18           JUDGE LEBOVITZ: Number 2 -- and you mentioned this  
19 several times in the brief, so I wanted to come to this issue.

20           MR. DOUGHTY: Mm-hmm.

21           JUDGE LEBOVITZ: He also says you can add water and  
22 water will carry off the polymers monomers.

23           MR. DOUGHTY: Sure.

24           JUDGE LEBOVITZ: Correct?

25           And you point and the examiner points to page 11 of the spec.

26           MR. DOUGHTY: Mm-hmm.

1 JUDGE LEBOVITZ: The examiner points to page 11 and says,  
2 "Appellant has admitted that the copolymer has water in it." If you look at  
3 page 11, it says that it -- it's what absorbs water present in the air.

4 So based on that and Vetter telling you that if you do the  
5 devolatilization step and there's water present, it will pull off some of the  
6 monomers, wouldn't that make it obvious to apply Vetter's step when you  
7 know that the copolymer has -- absorbs water?

8 And then you know from Vetter that the devolatilization step  
9 will not only remove the water, but it will also remove monomer --

10 MR. DOUGHTY: Okay. First, it's my understanding that  
11 there's nothing in the references -- aside from what we might cite in our  
12 specification, there's nothing in the references indicating that the particular  
13 polymer mixture in Lehmann that there's -- that there's water present or  
14 there's some volatile component that needs to be driven off.

15 JUDGE LEBOVITZ: But what about page 11 of your spec?

16 MR. DOUGHTY: But that's my specification.

17 JUDGE LEBOVITZ: But it seems to admit there no boiling  
18 constituents are mainly water absorbed from the moisture present in air or  
19 derived from the polymer -- this is a commercial form that you're talking  
20 about.

21 MR. DOUGHTY: Right, and it's the discovery that we can  
22 improve this commercial form by driving off this liquid. Like, for example,  
23 according to my client -- and this is not in the record.

24 But according to the client, there's no indication that even the  
25 commercial literature relating to the particular polymers that are used that  
26 this water occurs or that this water occurs through storage.

1               Like, that's -- basically, that's part and parcel of the discovery  
2   that makes the devolatilization step -- the discovery that the devolatilization  
3   step is going to improve the result. If that makes sense.

4               JUDGE ADAMS: So your position would be there's nothing in  
5   Lehmann that would suggest that there's monomers present.

6               MR. DOUGHTY: There's nothing in Lehmann that would  
7   suggest that monomers are present. That is not to say that there aren't  
8   monomers present, and in fact, that's what we've been trying to resolve.

9               JUDGE ADAMS: Isn't that what Vetter's also trying to  
10   resolve?

11              MR. DOUGHTY: Well, Vetter -- Vetter in passing mentions  
12   that this is possibly an alternative. But Vetter -- clearly the intent of Vetter  
13   is to remove these ammonium or amines that are added to the composition  
14   which are used to imidize a polymer.

15              So Vetter -- Vetter is dealing directly with this problem of  
16   introducing this extra agent in here, which is causing a chemical reaction, so  
17   they're trying to remove reactants from a polymer mixture.

18              JUDGE ADAMS: Sure. Part of what Vetter teaches is a  
19   successful method for reducing the content of residual monomers in the melt  
20   provides for the incorporation of a small quantity of water into the melt.  
21   During the subsequent devolatilization, the water evaporates and carries off  
22   with the monomer vapors.

23              MR. DOUGHTY: Sure.

24              JUDGE ADAMS: So Lehmann has this same  
25   polymethylmethacrylate as Vetter's talking about, and they're -- one of  
26   ordinary skill in the art would say, We melt these polymethylmethacrylates.

1 There's a likelihood you're going to have monomers there.

2 Vetter says, Let's go through and clean this stuff up. Not only  
3 all these other nasties that are in this preparation, but also let's take care of  
4 the monomers.

5 Not saying they're necessarily there, but there's probably a good  
6 likelihood that there are going to be these monomers present in this  
7 composition. How do you take care of that? You add a little bit of water  
8 and then evaporate it all.

9 Why isn't that a reasonable combination of references, even  
10 under KSR?

11 MR. DOUGHTY: I would just assert that there's -- well, this is  
12 certainly a possibility. I would say that there's nothing in the Lehmann  
13 reference in particular. The reference is being modified that indicates that  
14 this is a problem that needs to be remedied.

15 JUDGE ADAMS: Monomers are not problems with this  
16 particular composition that need to be addressed?

17 MR. DOUGHTY: According to the reference -- there's nothing  
18 in the reference that indicates that that is the case, okay?

19 While, in fact, that may be the case -- and in fact, that is the  
20 case -- that's not the precise problem that we're solving. But we have  
21 discovered that by devolatilizing that you can improve performance.

22 Now, that's not to say that there aren't monomers present in  
23 Lehmann, but there's no recognition that these monomers cause any problem  
24 with respect to the product that's being obtained.

25 JUDGE GREEN: But --

26 MR. DOUGHTY: But there's no indication -- I'm sorry.



1 JUDGE GREEN: But we read Lehmann as one of ordinary  
2 skill in the art would, right?

3 MR. DOUGHTY: Sure.

4 JUDGE GREEN: I think one of ordinary skill in the art with  
5 polymer chemistry and especially as used in the pharmaceutical arts would  
6 understand that most processes or some impurities are leftover monomers.

7 MR. DOUGHTY: Sure.

8 JUDGE GREEN: Very few reactions go to 100 percent. So  
9 even though Lehmann does not expressly say there are leftover monomers, I  
10 think one of ordinary skill in the art would understand, more likely than not,  
11 there are leftover.

12 MR. DOUGHTY: I agree with that and --

13 JUDGE GREEN: So if you're using this for a pharmaceutical  
14 formulation and a devolatilization -- I'm going to pronounce it wrong -- is  
15 just well known in the art for removing impurities. I mean, that's not an  
16 unusual step to do --

17 MR. DOUGHTY: Sure.

18 JUDGE GREEN: -- in these kinds of preparations.

19 So why would it have been unobvious to one of ordinary skill  
20 in the art, given the general understanding of the art, to go ahead and take  
21 out any monomers that may have been left over in Lehmann? Even though  
22 Lehmann doesn't expressly say that they're there, the understanding is most  
23 reactions don't go to 100 percent.

24 MR. DOUGHTY: Sure, but even if there are monomers  
25 present in a product, that doesn't necessarily indicate that they need to be  
26 removed, is what I'm saying. So basically, if Lehmann creates a capsule and

1 this capsule, for instance -- the end product has some monomer related --  
2 you know, in it.

3 JUDGE GREEN: So basically, your invention is a slightly  
4 more pure product than what was in Lehmann.

5 MR. DOUGHTY: A slightly --

6 JUDGE GREEN: I mean, pure impurities. You've taken out  
7 the water. You've taken out the leftover monomers by doing the  
8 devolatilization step.

9 MR. DOUGHTY: Sure.

10 JUDGE GREEN: Because you're saying that your product is  
11 just a little -- an improvement over Lehmann.

12 MR. DOUGHTY: It is.

13 JUDGE GREEN: So, I mean, there must have been a reason  
14 why your inventors decided that this product needed to be improved.

15 MR. DOUGHTY: Sure.

16 JUDGE GREEN: Because the Lehmann product, as it stands,  
17 is commercially available -- I mean, is commercially a viable product, right?

18 MR. DOUGHTY: I don't know that.

19 JUDGE GREEN: But we're assuming --

20 MR. DOUGHTY: Okay.

21 JUDGE GREEN: -- that it would probably -- because your  
22 argument is, Well, why would you improve upon Lehmann?

23 MR. DOUGHTY: Right.

24 JUDGE GREEN: But that -- I mean --

25 MR. DOUGHTY: Like, I'm not saying -- I guess I'm not saying  
26 -- I'm not trying to argue that Lehmann is, you know, asserting that it's

1 perfect or that there's nothing. I'm just saying that there's nothing  
2 affirmative in the reference that would lead one of ordinary skill in the art to  
3 make the improvement.

4 JUDGE GREEN: But what I'm saying is you have to read it in  
5 the light of what it would be recognized by the ordinary artisan, and the  
6 ordinary artisan would understand that there are monomers and impurities  
7 and let's go ahead and take those out with an extra step.

8 I don't see anything obvious -- I mean, anything unobvious  
9 about that given the general knowledge of one of ordinary skill in the art  
10 reading the Lehmann reference because one would understand that those  
11 monomers are present that there may be other impurities present.

12 MR. DOUGHTY: Okay. But would one recognize that there is  
13 something in the product of Lehmann that requires improvement?

14 Like, for example, sure, one could look at Lehmann and see that  
15 it's theoretically possible to improve the product, but if there's nothing in  
16 Lehmann that indicates that there's a problem with the product, like, what  
17 would drive someone to make that improvement, whereas --

18 JUDGE GREEN: But you have that all the time in an  
19 obviousness rejection.

20 You have a reference, usually a patent, that says this is a  
21 fantastic product, and then we make the combination, and using your  
22 analysis, we would probably never find obviousness because most -- most  
23 patents don't come out and say, Well, yeah, this product is great, but these  
24 are the problems here.

25 MR. DOUGHTY: Sure.

26 JUDGE GREEN: So I don't understand -- I mean, I'm saying

1 you have to broaden out Lehmann to be understood by the ordinary artisan.  
2 Lehmann doesn't have to come in and say, Well, these are the problems with  
3 my product, in order to make the obviousness rejection.

4 JUDGE ADAMS: I think you can also look at it from the  
5 perspective that what you're arguing is -- at least what I'm hearing you argue  
6 is that, yes, monomers may be present in Lehmann, but Lehmann doesn't say  
7 it's necessary to remove them.

8 MR. DOUGHTY: Sure.

9 JUDGE ADAMS: But Vetter says you can remove these  
10 monomers by doing this devolatilization step, so why would it not be  
11 obvious in view of these two references?

12 Sure, Lehmann says -- you know, we'll interpret Lehmann as  
13 saying it's not necessary to do it. We'll interpret Vetter as saying, Well, if  
14 you want to do it, here's how you do it, right?

15 MR. DOUGHTY: Sure.

16 JUDGE ADAMS: So why isn't that obvious? I mean, if you  
17 want to do it, go do it the way Vetter did it, and I think that's pretty much  
18 how you did it, right?

19 MR. DOUGHTY: I guess -- I guess -- I don't know. I guess  
20 my understanding of what Vetter is teaching, like, I would say that the  
21 overall thrust of Vetter is not towards -- I mean, the overall thrust of Vetter  
22 is toward addressing volatile additives to a process.

23 JUDGE GREEN: But Vetter does recognize that you use this  
24 particular step to remove impurities in general.

25 MR. DOUGHTY: In a process in which a volatile liquid is  
26 added subsequent to --

1 JUDGE GREEN: No. But in general.

2 MR. DOUGHTY: Sure.

3 JUDGE GREEN: You use this step to remove impurities.

4 That's how it's understood by the ordinary artisan, right? I mean, this is not  
5 a new step that you created.

6 MR. DOUGHTY: No. It's not.

7 JUDGE GREEN: It's been routinely used in chemical  
8 processes for many, many, many years.

9 MR. DOUGHTY: Sure.

10 JUDGE GREEN: So that's what -- you have to read Vetter in  
11 view of that knowledge of the ordinary artisan, and what Vetter suggests,  
12 you can use it to remove any impurities.

13 So even though it may be directed to a specific embodiment  
14 that Vetter was concerned with, Vetter doesn't say, Well, you can't use it to  
15 remove other impurities or you wouldn't use this in any other process.

16 MR. DOUGHTY: Okay.

17 JUDGE GREEN: Do you understand?

18 MR. DOUGHTY: I understand what you're saying, and I  
19 guess, without getting into the particulars, I certainly see where -- I see what  
20 you're saying, and there's the possibility of making the combination.

21 And clearly, you know, the elements are out there and I -- I  
22 mean, I would just stand on the arguments that I made that one of ordinary  
23 skill in the art wouldn't have been led in that position.

24 JUDGE GREEN: But KSR, I mean, really leads us back to  
25 what would have been understood by the ordinary artisan, that we don't have  
26 to have a specific statement leaning towards --

1 MR. DOUGHTY: I agree.

2 JUDGE GREEN: -- the combination.

3 MR. DOUGHTY: I agree with that.

4 JUDGE GREEN: And even obvious to try may be sufficient in  
5 -- this actually may even be an obvious to try. It may have been obvious to  
6 try to further remove all impurities in the context of the Lehmann in order to  
7 obtain a more -- a product that's more predictable as you get it out,  
8 especially if you're doing pharmaceutical uses.

9 MR. DOUGHTY: Yeah. I mean, of course you're going to  
10 have to make your own sort of weighing in whether or not it's obvious or  
11 not.

12 And the one thing that I would ask that you also take into  
13 consideration is the sort of limited data that's provided in the present  
14 specification. It's not ideal.

15 There's only one example that's straight on point to what we're  
16 talking about now, but if you look at example 1 and example 3. Example 1  
17 is an example according to the present invention, and example 3 is the  
18 identical example; however, there's no venting going on in extrusion, so  
19 there's no additional devolatilization step.

20 And as a result of adding the devolatilization, example 1  
21 provides superior capsules that are obtained in example 3, so --

22 JUDGE LEBOVITZ: Can we go slowly through that. The  
23 examiner says that the examples are not comparative because the first  
24 example, I think, was at 160 and the second example was at 180.

25 So the examples are not comparative or the showing's not side-  
26 by-side because conditions were different. He points to the temperature as

1 being different, 160 to 180, and also the release agent.

2 MR. DOUGHTY: Right. I think that that is true in the  
3 comparison between example 1 and example 2.

4 JUDGE LEBOVITZ: Yes.

5 MR. DOUGHTY: And example 2 is addressing the situation in  
6 which there is a different amount of mold release agent.

7 COURT REPORTER: I'm sorry. A different amount of what?

8 MR. DOUGHTY: There's a different amount of mold release  
9 agent.

10 JUDGE LEBOVITZ: How do you spell mold?

11 MR. DOUGHTY: M-O-L-D.

12 JUDGE LEBOVITZ: Okay. I guess the English spelling is M-  
13 O-U-L-D.

14 MR. DOUGHTY: Yeah, yeah.

15 JUDGE LEBOVITZ: So --

16 MR. DOUGHTY: So basically -- go ahead.

17 JUDGE LEBOVITZ: Example 1 and example 2 are not  
18 comparative?

19 MR. DOUGHTY: Well, example 2 is comparative, but it's  
20 comparative in a different regard than the conversation that we've been  
21 having here. So example 2 is addressing the different amount of mold  
22 release agent, okay?

23 And there are differences in the processing temperature which  
24 may or may not be indicative of whether it's commensurate. It's whether it's  
25 a good side-by-side comparison.

26 The applicants read the review that it was, but I think more

1 germane to the argument that we're having today is the comparison between  
2 example 1 and example 3, which is directly on point to the deficiency of  
3 Lehmann that we've been discussing, namely the devolatilization step.

4 JUDGE LEBOVITZ: And can you explain the difference  
5 between 1 and 3?

6 MR. DOUGHTY: Well, the only difference between 1 and 3 is  
7 that there is a devolatilization step in example 1 and there is no  
8 devolatilization step in example 3; namely in a particular apparatus, the  
9 lower part of the extrusion or the extrusion chamber has vents. This is the  
10 devolatilization.

11 JUDGE LEBOVITZ: The vents are closed.

12 MR. DOUGHTY: Right. So they close the vents.

13 JUDGE LEBOVITZ: But that's true, but if we go down the  
14 path that Vetter suggests, adding a volatilization step to it --

15 MR. DOUGHTY: Sure.

16 JUDGE LEBOVITZ: -- then any advantages would not make  
17 the subject matter nonobvious. You have to have unexpected results.

18 Any -- I think there's case law, Baxter, where it says that if  
19 you've got -- a process was suggested by the prior art, any advantages flow  
20 with the process. It doesn't flow with the suggested process. It doesn't make  
21 it nonobvious.

22 So you've got to have more than an advantage, an unappreciated  
23 advantage. You've got to have unexpected results.

24 MR. DOUGHTY: And the applicant submits that obtaining  
25 this improved quality in the capsule is unexpected. I mean --

26 JUDGE GREEN: But you said "unexpected," and if you



1 remove impurities, you'll get a better quality product.

2 MR. DOUGHTY: I mean, I can't -- there's nothing in the  
3 record. I can't speak to that. You know, I'm not --

4 JUDGE GREEN: But it seems to me that's what you're going  
5 to get when you start removing impurities, is you're going to get something  
6 that's more predictable because it has a more predictable composition and  
7 everything else. You've taken that step --

8 MR. DOUGHTY: That may or may not be true. I mean, the  
9 impurities are impurities in the sense that they're not the desired product that  
10 you're ending up with, but as to the effect that it's going to have on the  
11 physical structure that you're trying to obtain, I mean, it's --

12 JUDGE GREEN: Yeah, but it's just hard to say without further  
13 -- with just this one paragraph at the end of page 19 that that's unexpected.

14 MR. DOUGHTY: I understand. I'm just asking that it be  
15 considered and given weight with everything else that's in the record.

16 JUDGE ADAMS: All right. You have a few minutes left. Is  
17 there anything else you want to --

18 MR. DOUGHTY: No. That's it.

19 (Whereupon, the proceedings at 10:14 a.m. were concluded.)  
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